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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,048	08/10/2001	Thomas L. Cantor		7860

7590 05/18/2005

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EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/928,048	**Applicant(s)** CANTOR, THOMAS L.	
	Examiner Gary W. Counts	**Art Unit** 1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *1-9, 17-25*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached continuation sheet..
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

LONG V. LE
SUPERVISORY PATENT EXAMINER 03/13/05
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Continuation of 11 NOTE: Applicants arguments are not found persuasive because of reasons of record and as further stated below.

Applicant argues that it is unclear what basis the Examiner has to distinguish the present claims from the Federal Circuit opinions cited in the previous response. Enzo Biochem. V. Gen-Probe, Inc., 323 F. 3d 956, 964 (Fed. Cir. 2002); Noelle v. Lederman. 69 USPQ2d 1508, 1513-14 (FED. Cir. 2004). These cases and the PTO Guidelines state that the written description requirement for an antibody is satisfied if the application discloses binding of the antibody to a fully characterized antigen. The *Noelle* Court summarized as follows

> Therefore, based on our precedent as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

This is not found persuasive because as stated in the previous office action the fact patterns disclosed in In Enzo biochem. V. Gen-Probe, Inc., 323 F.3d 956,964 (Fed. Cir. 2002) and In Noelle v. Lederman, 69 USPQ2d 1508, 1513-14 (Fed. Cir. 2004) are different from that of the instant application. The Noelle antibody is for an antigen and does not posses special distinguishing properties. The instant application not only requires the creation of an antibody but also requires the creation of a special antibody (ie. the ability of the antibody to discriminate between the CIP presenting the epitope and the cyclase activating parathyroid hormone).

Applicant argues that the appropriate "Written Description" question in this situation is not about physical possession. It is provided in the Examiner's comments,

where the Examiner states: "The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed had possession of the claimed invention." This is not found persuasive because Applicant has not shown possession either actual or constructive to prove Applicant had an antibody that is able to distinguish a peptide sequence for CIP that present an epitope available for antibody binding in CIP, but does not bind to the sample peptide sequence in cylcase activating parathyroid hormone.

Applicant argues that the Examiner is not at liberty to impose an extra-statutory "physical possession" requirement on the Applicant, where neither the written description nor the enablement standards includes one. This is not found persuasive because the Applicant has not provided possession of any kind either actual or constructive. The applicant has not show that such an antibody (as described above) exits or a predictability how to produce one or more of the antibodies.

Applicant argues that many antibodies to PTH peptides were well known before the application was filed, and methods for producing antibodies against PTH and Fragments of PTH were routine. Applicant states that the only real issue is obtaining one with the right selectivity. This is not found persuasive because this is not the only real issue. As stated above the Applicant has not disclose possession either actual or constructive of an antibody that is able to distinguish a peptide sequence for CIP that present an epitope available for antibody binding in CIP, but does not bind to the sample peptide sequence in cylcase activating parathyroid hormone.

Applicant provides Exhibits A-F for showing antibodies which bind to shorter peptides while not binding to longer peptides. These exhibits are not found persuasive because as stated in the previous office action the instantly recited claims are totally dependent on the ability of the antibody to discriminate between the CIP presenting the epitope and the cyclase activating parathyroid hormone and these references haven't shown such antibodies which perform in this manner.

Applicant provides Exhibits G-H stating that the T-PTH antibody of the D'Amour reference, which exhibits a selectivity pattern potentially similar to that of the disclosed invention, was produced before the current application. This is not found persuasive of reasons of record and further because as stated above the Applicant has not provided possession of any kind either actual or constructive of an antibody that is able to distinguish a peptide sequence for CIP that present an epitope available for antibody binding in CIP, but does not bind to the sample peptide sequence in cylcase activating parathyroid hormone nor has Applicant shown that they can predictably reproduce the antibody with anything.

With respect to the Declaration filed 04/18/05, the Declaration is not found persuasive because it appears the declaration is a description of the D'Amour reference that discusses the PTH structure and assay and does not explain what one in the art would expect. The declaration does not provide anything that has not already been discussed on the record.

With respect to Applicants arguments directed to 112 first enablement. This is not found persuasive because of reason of record and for reasons stated above.

Further, Applicant has not provided possession of any kind either actual or constructive of an antibody that is able to distinguish a peptide sequence for CIP that present an epitope available for antibody binding in CIP, but does not bind to the sample peptide sequence in cylcase activating parathyroid hormone nor has Applicant shown that they can predictably reproduce the antibody with anything. And the art indicates that such an antibody is not well known in the art. Also, applicants own statements in the specification indicate that such an antibody is not known in the art (For instance, on page 5, second paragraph, lines 9-21 in the specification. The applicant discloses that in making a direct measurement of CIP, one can use an antibody or antibody fragment specific for a peptide sequence for CIP which by virtue of the unique CIP protein conformation is available for antibody binding but this same epitope is not available for antibody bind in CAP by virtue of the unique CAP protein conformation of CAP, in an amount sufficient to behind the CIP present, and thus, enable immunoassay measurement. In other words, conformation changes between CAP and CIP do not make the CIP binding site available on CAP. Such a domain has been identified that functions in the opposite manner). Therefore, since Applicant has not disclosed an antibody that is able to distinguish a peptide sequence for CIP that present an epitope available for antibody binding in CIP, but does not bind to the sample peptide sequence in cylcase activating parathyroid hormone nor has Applicant shown that they can predictably reproduce the antibodies. Thus one cannot claim unexpected results without results and one of ordinary skill does not have the knowledge that there is a

success and thus one of ordinary skill in the art would not expect to obtain an antibody that discriminates between CIP (7-84) and CAP (1-84).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
May 11, 2005